K091813

MEDTRONIC Sofamor Danek
SOVEREIGN™ Spinal System
November 2009

NOV 17 2009

I. **Company:** Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

Contact: Michael Scott
Regulatory Affairs Specialist

II. **Product Name:** SOVEREIGN™ Spinal System
Common Name: Intervertebral Fusion Device
Classification: 21 CFR 888.3080 – Product Code: MAX

III. **Description:** The SOVEREIGN™ Spinal System is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The accompanying cover plate is designed to resist screw backout and must be used when screws are implanted. The implant is lens-shaped with three holes for placement of titanium screws. This device is intended to be radiolucent and the interior space of the product is to be used with bone graft.

The SOVEREIGN™ Spinal System interbody device is manufactured from PEEK Optima® (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.

IV. **Indications for Use:** The SOVEREIGN™ Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach.

The SOVEREIGN™ interbody device may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the SOVEREIGN™ interbody device is intended to be used with the three titanium alloy screws and the accompanying cover plate. If the physician chooses to use less than three or none of the provided screws, then additional supplemental fixation which has

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been cleared by the FDA for use in the lumbar spine must be used to augment stability. The accompanying cover plate MUST be used anytime the device is used with any number of screws.

V. **Substantial Equivalence:** Documentation including a risk analysis was provided which demonstrated the subject intervertebral devices to be substantially equivalent to INTREPID™ Spinal System components previously cleared in K080083 (SE 04/10/2008). Minor changes have been made to the Information for Use labeling. These changes consist of modified indications, a modified device description and additional contraindications and NOTA BENE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Medtronic Sofamor Danek
% Mr. Michael Scott
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K091813
Trade/Device Name: SOVEREIGN™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: November 5, 2009
Received: November 10, 2009

Dear Mr. Scott:

This letter corrects our substantially equivalent letter of November 17, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K091813

Device Name: SOVEREIGN™ Spinal System

Indications for Use:

The SOVEREIGN™ Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X___ OR Over-The-Counter Use _____
Per 21 CFR 801.109

Janette C for Mark Melkerson
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091813